

क्रम संख्यांक	औषधि विनिर्मिति का ब्रांड नाम
290.	वाईमाडा 24/26 एमजी टैबलेट 14
291.	वाईसोलोन 10 एमजी टैबलेट डीटी 15
292.	वाईसोलोन 5 एमजी टैबलेट डीटी 15
293.	ज़ोन 1000 एमजी इन्जेक्शन 5 एमएल
294.	ज़ेविसेफ्टा 200/500 एमजी वायल 10 एमएल
295.	ज़ेडेक्स 4/5/50 एमजी सिरप 100 एमएल
296.	जीरोडोल पी 100/325 एमजी टैबलेट 10
297.	जीरोडोल एसपी 100/325/15 एमजी टैबलेट 10
298.	ज़िफ्री 200 एमजी टैबलेट 10
299.	ज़ोरील-एम 2/500 एमजी टैबलेट 20
300.	ज़ोस्टम 1000/500 एमजी इन्जेक्शन 1 । ” ।

[फा. सं. एक्स. 11035/32/2019-डीआर]

डॉ. मनदीप के भण्डारी, संयुक्त सचिव

टिप्पण:- औषधि नियम, 1945 अधिसूचना संख्यांक एफ. 28-10/45-एच (1), तारीख 21 दिसम्बर, 1945 द्वारा भारत के राजपत्र में प्रकाशित किए गए थे और अधिसूचना संख्यांक सा.का.नि. 654(अ), तारीख 24 अगस्त, 2022 द्वारा अंतिम बार संशोधित किए गए थे।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 17th November, 2022.

G.S.R. 823(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945 was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 448(E), dated the 14th June, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 15th June, 2022;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

- (1) These rules may be called the Drugs (Eighth Amendment) Rules, 2022.
- (2) They shall come into force on the 1st day of August, 2023.
- In the Drugs Rules, 1945 (hereinafter to be referred as the said rules), in rule 96, after sub-rule (5) and before the explanation, the following sub-rules shall be inserted, namely:—
 - “(6) The manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.
 - (7) The stored data or information referred to in sub-rule (6) shall include the following particulars, namely:—
 - unique product identification code;
 - proper and generic name of the drug;

- (iii) brand name;
- (iv) name and address of the manufacturer;
- (v) batch number;
- (vi) date of manufacturing;
- (vii) date of expiry; and
- (viii) manufacturing licence number.”.

3. In the said rules, after Schedule H1, the following Schedule shall be inserted, namely:—

“SCHEDULE H2

[See sub-rules (6) and (7) of rule 96]

Serial number	Brand name of drug formulation
1.	ACILOC 150 MG TABLET 30
2.	ACILOC 300 MG TABLET 20
3.	ACTEMRA 400 MG INJECTION 1
4.	ACTRAPID HUMAN 40 IU INJECTION 10 ML
5.	AEROCORT WITH DOSE COUNTER 50/50 MCG INHALER 200 MDI
6.	AJADUO 25/5 MG TABLET 10
7.	ALLEGRA 120 MG TABLET 10
8.	ALLEGRA 180 MG TABLET 10
9.	AMBISOME 50 MG INJECTION 20 ML
10.	AMICIN 500 MG INJECTION 2 ML
11.	AMLOKIND-AT 50/5 MG TABLET 10
12.	ASCORIL D PLUS NEW 5/2/10 MG SYRUP 100 ML
13.	ASCORIL LS 1/30/50 MG SYRUP 100 ML
14.	ASCORIL PLUS 50/1.25/2 MG EXPECTORANT 120 ML
15.	ASTHAKIND DX 5/2/15 MG SYRUP 100 ML
16.	ASTHALIN 100 MCG INHALER 200 MDI
17.	AUGMENTIN DUO 500/125 MG TABLET 10
18.	AVOMINE 25 MG TABLET 10
19.	AXCER 90 MG TABLET 14
20.	AZEE 500 MG TABLET 5
21.	AZITHRAL 500 MG TABLET 5
22.	BECOSULES CAPSULE 20
23.	BECOSULES Z CAPSULE 20
24.	BETADINE 10 % OINTMENT 20 GM
25.	BETADINE 10 % SOLUTION 100 ML
26.	BETADINE MINT 2 % GARGLE 100 ML
27.	BETNESOL 0.5 MG TABLET 20
28.	BETNOVATE C 0.1/3 % CREAM 30 GM
29.	BETNOVATE N 0.1/0.5 % CREAM 20 GM
30.	BETNOVATE N 0.1/0.5 % CREAM 25 GM
31.	BETT 0.5 ML INJECTION 0.5 ML
32.	BEVON SYRUP 200 ML
33.	BIO D3 MAX 500 MG/0.25MCG/400MCG/120MG CAPSULE 15
34.	BRILINTA 90 MG TABLET 14

Serial number	Brand name of drug formulation
35.	BRO ZEDEX 50/1.25/4 MG SYRUP 100 ML
36.	BUDECORT 0.5 MG RESPULES 2 ML
37.	CALCIROL 60000 IU GRANULES 1 GM
38.	CALDIKIND PLUS 500 MG/0.25MCG/400MCG/60MG CAPSULE 10
39.	CALPOL 500 MG TABLET 15
40.	CALPOL 650 MG TABLET 15
41.	CALPOL PEAD 250 MG SUSPENSION 60 ML
42.	CANDIFORCE 200 MG CAPSULE 7
43.	CCM 250 MG TABLET 40
44.	CEFAKIND 500 MG TABLET 10
45.	CEFTUM 500 MG TABLET 4
46.	CEPODEM 200 MG TABLET 10
47.	CHYMORAL FORTE 100000 IU TABLET 20
48.	CIDMUS 24/26 MG TABLET 14
49.	CILACAR 10 MG TABLET 15
50.	CIPREMI 100 MG INJECTION 1
51.	CLARIBID 500 MG TABLET 10
52.	CLAVAM 500/125 MG TABLET 10
53.	CLEXANE 40 MG INJECTION 0.4 ML
54.	CLEXANE 60 MG INJECTION 0.6 ML
55.	COBADEX CZS TABLET 15
56.	CODISTAR 4/10 MG SYRUP 100 ML
57.	COMBIFLAM 400/325 MG TABLET 20
58.	CONCOR 5 MG TABLET 10
59.	COREX DX 4/10 MG SYRUP 100 ML
60.	CREMAFFIN PLUS SF 1.25 ML/3.75ML/3.33MG LIQUID 225 ML
61.	CYPON 275/2 MG SYRUP 200 ML
62.	CYRA D 30/20 MG TABLET SR 10
63.	DALACIN C 300 MG CAPSULE 10
64.	DECA DURABOLIN 50 MG INJECTION 1
65.	DEFCORT 6 MG TABLET 10
66.	DERIPHYLLIN 25.3/84.7 MG INJECTION 2 ML
67.	DEROBIN 1.15/1.15/5.3 % OINTMENT 30 GM
68.	DEXONA (VIAL) 4 MG INJECTION 2 ML
69.	DEXORANGE 160 MG/0.5MG/7.5MCG SYRUP 200 ML
70.	DOLO 650 MG TABLET 15
71.	DOLONEX 20 MG TABLET DT 15
72.	DOXINATE 10/10 MG TABLET 30
73.	DOXT SL 100 MG/5BIU CAPSULE 10
74.	DOXY 1 FORTE L DR 100 MG/5BIU CAPSULE 10
75.	DULCOFLEX 5 MG TABLET 10
76.	DUOLIN 3 1.25 MG/500MCG RESPULES 3 ML

Serial number	Brand name of drug formulation
77.	DUPHASTON 10 MG TABLET 10
78.	DYDROBOON 10 MG TABLET 10
79.	DYNAPAR AQ 75 MG INJECTION 1 ML
80.	EASY SIX PREFILLED SYRINGE 0.5 ML
81.	ECOSPRIN AV 10/75 MG CAPSULE 15
82.	ECOSPRIN GOLD 75/20/75 MG TABLET 15
83.	ELAXIM 40 MG INJECTION 1
84.	ELECTRAL SACHET 21.8 GM
85.	ELIQUIS 2.5 MG TABLET 10
86.	ELIQUIS 5 MG TABLET 10
87.	ELTROXIN 100 MCG TABLET 120
88.	ENTEROGERMINA 2 BIU ORAL SUSPENSION 5 ML
89.	EXHEP 40 MG PREFILLED SYRINGE 0.4 ML
90.	FABIFLU 200 MG TABLET 34
91.	FABIFLU 400 MG TABLET 17
92.	FABIFLU COPACK 800 MG TABLET 18
93.	FARONEM 200 MG TABLET 10
94.	FARONEM 300 MG TABLET ER 10
95.	FORACORT 20/500 MCG RESPULES 2 ML
96.	FORACORT 6/200 MCG ROTACAP 30
97.	FORACORT 6/400 MCG ROTACAP 30
98.	FORXIGA 10 MG TABLET 14
99.	GABAPIN NT 400/10 MG TABLET 15
100.	GALVUS 50 MG TABLET 15
101.	GALVUS MET 50/1000 MG TABLET 15
102.	GALVUS MET 50/500 MG TABLET 15
103.	GEFTINAT 250 MG TABLET 30
104.	GELUSIL MPS 250/50/250 MG LIQUID 200 ML
105.	GEMCAL 500 MG/0.25MCG/7.5MG CAPSULE 15
106.	GEMER 2/500 MG TABLET 10
107.	GIBTULIO 25 MG TABLET 10
108.	GLUCONORM-G 2/500 MG TABLET 15
109.	GLYCOMET GP 1/500 MG TABLET 15
110.	GLYCOMET GP 2/500 MG TABLET SR 15
111.	GLYNASE MF 5/500 MG TABLET 10
112.	GLYXAMBI 25/5 MG TABLET 10
113.	GRILINCTUS 60/2.5/5/50 MG SYRUP 100 ML
114.	GUDCEF 200 MG TABLET 10
115.	GUDCEF CV 200/125 MG TABLET 10
116.	HCQS 200 MG TABLET 15
117.	HEXAXIM INJECTION 0.5 ML
118.	HUCOG HP 5000 IU INJECTION 1 ML

Serial number	Brand name of drug formulation
119.	HUMINSULIN 30/70 100 IU CARTRIDGE 3 ML
120.	INFANRIX HEXA INJECTION 0.5 ML
121.	ISTAMET 50/500 MG TABLET 15
122.	IVABRAD 5 MG TABLET 15
123.	IVERMECTOL NEW 12 MG TABLET 2
124.	JALRA M 50/500 MG TABLET 15
125.	JANUMET 50/1000 MG TABLET 15
126.	JANUMET 50/500 MG TABLET 15
127.	JANUVIA 100 MG TABLET 7
128.	JARDIANCE 10 MG TABLET 10
129.	JARDIANCE 25 MG TABLET 10
130.	KABIMOL 1000 MG INFUSION 100 ML
131.	KARVOL PLUS CAPSULE 10
132.	KENACORT 40 MG INJECTION 1 ML
133.	KETOROL 10 MG TABLET DT 15
134.	KETOSTERIL TABLET 20
135.	LANTUS 100 IU CARTRIDGE 3 ML
136.	LANTUS SOLOSTAR 100 IU DISPOSABLE PEN 3 ML
137.	LEVERA 500 MG TABLET 15
138.	LEVIPIL 500 MG TABLET 10
139.	LIBRAX 2.5/5 MG TABLET 20
140.	LIMCEE CHEW ORANGE 500 MG TABLET 15
141.	LIPAGLYN 4 MG TABLET 10
142.	LMWX 40 MG INJECTION 0.4 ML
143.	LOBATE GM NEO 0.05/0.5/2 % CREAM 15 GM
144.	LONOPIN 40 MG INJECTION 0.4 ML
145.	LOSAR 50 MG TABLET 15
146.	LOSAR H 50/12.5 MG TABLET 15
147.	MACBERY XT 50/1.25/4 MG SYRUP 100 ML
148.	MAGNEX FORTE 1000/500 MG INJECTION 1
149.	MANFORCE 100 MG TABLET 4
150.	MANFORCE 50 MG TABLET 9
151.	MAXTRA 5/2 MG SYRUP 60 ML
152.	MEFTAL SPAS 10/250 MG TABLET 10
153.	MEGALIS 20 MG TABLET 4
154.	MEGANEURON OD PLUS 1500 MCG CAPSULE 10
155.	MENACTRA INJECTION 0.5 ML
156.	MERO 1000 MG INJECTION 1
157.	MEROMAC 1000 MG INJECTION 1
158.	MERONEM 1000 MG INJECTION 1
159.	MEROZA 1000 MG INJECTION 1 ML
160.	MIFEGEST KIT 200 MG/200MCG TABLET 1

Serial number	Brand name of drug formulation
161.	MIKACIN 500 MG INJECTION 2 ML
162.	MINIPRESS XL 5 MG TABLET XL 30
163.	MIXTARD HM PENFILL 30/70 100 IU INJECTION 3 ML
164.	MIXTARD HUMAN 30/70 40 IU INJECTION 10 ML
165.	MIXTARD HUMAN 50/50 40 IU INJECTION 10 ML
166.	MONOCEF 1000 MG INJECTION 5 ML
167.	MONOCEF O 200 MG TABLET 10
168.	MONOCEF SB 1000/500 MG INJECTION 1
169.	MONTAIR LC 10/5 MG TABLET 15
170.	MONTAZ 1000/125 MG INJECTION 1
171.	MONTEK-LC 10/5 MG TABLET 10
172.	MONTICOPE 10/5 MG TABLET 10
173.	MOX 500 MG CAPSULE 15
174.	MOX CV 500/125 MG TABLET 10
175.	MOXCLAV 500/125 MG TABLET 10
176.	MOXIKIND CV 500/125 MG TABLET 10
177.	MUCAINE MINT 10/291/98 MG GEL 200 ML
178.	MUCINAC SF ORANGE 600 MG TABLET 10
179.	NEBICARD 5 MG TABLET 10
180.	NEFROSAVE 150/500 MG TABLET 15
181.	NEUROBION FORTE TABLET 30
182.	NEXPRO 40 MG TABLET 15
183.	NEXPRO RD 30/40 MG CAPSULE 10
184.	NIKORAN 5 MG TABLET 20
185.	NISE 100 MG TABLET 15
186.	NITROCONTIN 2.6 MG TABLET CR 30
187.	NOVOMIX 100 IU CARTRIDGE 3 ML
188.	NOVOMIX 30/70 MG FLEXPEN 3 ML
189.	NOVORAPID 100 IU CARTRIDGE 3 ML
190.	NUROKIND LC 500 MG/1.5MG/1500MCG TABLET 15
191.	NUROKIND PLUS RF 1500 MCG CAPSULE 10
192.	O2 200/500 MG TABLET 10
193.	OMEZ 20 MG CAPSULE 20
194.	OMEZ D 30/20 MG CAPSULE SR 15
195.	OMNIKACIN 500 MG INJECTION 2 ML
196.	ONDERO 5 MG TABLET 10
197.	ONDERO MET 2.5/500 MG TABLET 10
198.	OROFER FCM INJECTION 10 ML
199.	OROFER-XT 100/1.5 MG TABLET 10
200.	OROFER-XT PLUS 30 MG/500MCG/500MCG SUSPENSION 200 ML
201.	OTRIVIN OXY FAST RELIEF 0.05 % SPRAY 10 ML
202.	OVRAL L 0.03/0.15 MG TABLET 21

Serial number	Brand name of drug formulation
203.	OXRA 10 MG TABLET 14
204.	PAN 40 MG TABLET 15
205.	PAN D 30/40 MG CAPSULE 15
206.	PANDERM PLUS PLUS 0.05/0.5/2 % CREAM 15 GM
207.	PANTIN IV 40 MG INJECTION 10 ML
208.	PANTOCID 40 MG TABLET 15
209.	PANTOCID DSR 30/40 MG CAPSULE 15
210.	PANTODAC 40 MG TABLET 15
211.	PANTODAC DSR 30/40 MG CAPSULE 15
212.	PANTOP 40 MG INJECTION 10 ML
213.	PANTOP 40 MG TABLET 15
214.	PANTOP D 10/20 MG CAPSULE 10
215.	PANTOP D SR 30/40 MG CAPSULE SR 10
216.	PHENSEDYL COUGH LINCTUS 4/10 MG SYRUP 100 ML
217.	PIPZO 4000/500 MG INJECTION 10 ML
218.	PRACTIN 4 MG TABLET 10
219.	PREGA NEWS KIT 6
220.	PREVENAR 13 INJECTION 0.5 ML
221.	R.B TONE SYRUP 200 ML
222.	RABLET-D 30/20 MG CAPSULE 10
223.	RANTAC 150 MG TABLET 30
224.	RAZO 20 MG TABLET 15
225.	RAZO D 30/20 MG TABLET 15
226.	REFRESH TEARS 0.5 % EYE DROPS 10 ML
227.	REJUNEX-CD3 TABLET 10
228.	REMDAC 100 MG INJECTION 1
229.	ROSUVAS 10 MG TABLET 15
230.	ROSUVAS 20 MG TABLET 10
231.	RYZODEG 2.56/1.05 MG PENFILL 3 ML
232.	SARIDON 250/50/150 MG TABLET 10
233.	SEROFLO 50/250 MCG ROTACAP 30
234.	SHELCAL 500 MG/250IU TABLET 15
235.	SHELCAL XT 500 MG/2000IU/1500MCG/1MG/20MG TABLET 15
236.	SILODAL 8 MG TABLET 10
237.	SILODAL D 8/0.5 MG TABLET 10
238.	SINAREST 125/5/1 MG SYRUP 60 ML
239.	SINAREST NEW 500/10/2 MG TABLET 10
240.	SINAREST NEW 500/10/2 MG TABLET 15
241.	SKINLITE 2/0.1/0.025 % CREAM 25 GM
242.	SOMPRAZ D 30/40 MG CAPSULE 15
243.	SPASMO PROXYVON PLUS 10/325/50 MG CAPSULE 8
244.	SPEGRA 50/200/25 MG TABLET 30

Serial number	Brand name of drug formulation
245.	STAMLO 5 MG TABLET 30
246.	STAMLO BETA 50/5 MG TABLET 15
247.	STEMETIL 5 MG TABLET MD 15
248.	SUCRAFIL O 1000/20 MG GEL 200 ML
249.	SUMO 100/325 MG TABLET 15
250.	SUMO L IV 1000 MG INFUSION 100 ML
251.	SUPRADYN TABLET 15
252.	SYNFLORIX INJECTION 1
253.	T BACT 2 % OINTMENT 15 GM
254.	T BACT 2 % OINTMENT 5 GM
255.	TARGOCID 400 MG INJECTION 1 ML
256.	TAXIM O 200 MG TABLET 10
257.	TAZOMAC 4000/500 MG INJECTION 2 ML
258.	TELEKAST-L 10/5 MG TABLET 15
259.	TELMA 40 MG TABLET 30
260.	TELMA AM 40/5 MG TABLET 15
261.	TELMA H 40/12.5 MG TABLET 15
262.	TELMIKIND 40 MG TABLET 10
263.	TELMIKIND AM 40/5 MG TABLET 10
264.	TELMIKIND H 40/12.5 MG TABLET 10
265.	THROMBOPHOB OINTMENT 20 GM
266.	THYRONORM 100 MCG TABLET 120
267.	THYRONORM 25 MCG TABLET 120
268.	THYRONORM 50 MCG TABLET 120
269.	TOSSEX NEW 4/10 MG SYRUP 100 ML
270.	TRAJENTA 5 MG TABLET 10
271.	TRESIBA FLEXTOUCH 100 IU DISPOSABLE PEN 3 ML
272.	TUSQ DX 5/2/15 MG SYRUP 100 ML
273.	UDILIV 150 MG TABLET 15
274.	UDILIV 300 MG TABLET 15
275.	ULTRACET 325/37.5 MG TABLET 15
276.	UNIENZYME TABLET 15
277.	UNWANTED 72 1.5 MG TABLET 1
278.	UNWANTED KIT 200 MG/200MCG TABLET 1
279.	UPRISE D3 60000 IU CAPSULE 8
280.	URIMAX 0.4 MG CAPSULE 20
281.	URIMAX D 0.4/0.5 MG TABLET 15
282.	URSOCOL 300 MG TABLET 15
283.	VARILRIX INJECTION 0.5 ML
284.	VELOZ D 30/20 MG CAPSULE SR 10
285.	VELPANAT 400/100 MG TABLET 28
286.	VERTIN 16 MG TABLET 15

Serial number	Brand name of drug formulation
287.	VOLINI 1.16 % SPRAY 40 GM
288.	VORIER 200 MG TABLET 4
289.	VOVERAN SR 100 MG TABLET SR 15
290.	VYMADA 24/26 MG TABLET 14
291.	WYSOLONE 10 MG TABLET DT 15
292.	WYSOLONE 5 MG TABLET DT 15
293.	XONE 1000 MG INJECTION 5 ML
294.	ZAVICEFTA 2000/500 MG VIAL 10 ML
295.	ZEDEX 4/5/50 MG SYRUP 100 ML
296.	ZERODOL P 100/325 MG TABLET 10
297.	ZERODOL SP 100/325/15 MG TABLET 10
298.	ZIFI 200 MG TABLET 10
299.	ZORYL-M 2/500 MG TABLET 20
300.	ZOSTUM 1000/500 MG INJECTION 1.”.

[No. X.11035/32/2019-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

Note: The Drug Rules, 1945 were published in the Official Gazette *vide* notification number F. 28-10/45-H(1), dated 21st the December, 1945 and were last amended *vide* notification number G.S.R. 654(E), dated the 24th August, 2022.